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Attorney Docket No: UNIV0162

Group Art Unit: 3715

Examiner: Utama, Robert J.

APPEAL BRIEF

March 30, 2009

TO THE DIRECTOR OF THE PATENT AND TRADEMARK OFFICE:

1 STATEMENT OF THE REAL PARTY IN INTEREST

2 The real party in interest in this appeal is hereby identified as the University of
3 Washington, since all right and title in the invention and in the patent application on
4 appeal has been assigned to the University of Washington, as evidenced by a chain of
5 title from the inventors in the patent application identified above to the current
6 assignee, as shown below.

7 1. An assignment of all rights and title in the present patent application was
8 made by inventors **Raymond W. Sze** (assignment executed on February 10, 2004)
9 and **Anh-Vu Ngo** (assignment executed on January 23, 2004) to the **University of**
10 **Washington**. The assignments were recorded in the U.S. Patent and Trademark
11 Office on March 22, 2004 at Reel 015124, Frame 0142 and on March 22, 2004 at
12 Reel 015126, Frame 0538, respectively.

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STATEMENT OF RELATED CASES

No other prior or pending appeals, interferences, or judicial proceedings are known to any inventors, any attorneys or agents who prepared or prosecuted the application on appeal and any other person who was substantively involved in the preparation or prosecution of the application on appeal that are related to or will directly affect or be directly affected by or have a bearing on the Board's decision in this pending appeal.

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JURISDICTIONAL STATEMENT

The Board has jurisdiction under 35 U.S.C. § 134(a).

Examiner Robert Utama of Group Art Unit 3725 mailed a final rejection on October 28, 2008, setting a three-month shortened statutory period for response. The time for responding to the final rejection expired on January 28, 2009.

Appellants filed a timely Notice of Appeal on January 28, 2009.

Appellants filed this timely Appeal Brief on March 30, 2009.

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TABLE OF AUTHORITIES

Statutes

35 U.S.C. § 103(a) 9, 14, 17, 19, 21, 22, 23, 24, 31, 33, 35, 37

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STATUS OF AMENDMENTS

An amendment filed on January 28, 2009, after the final rejection, was entered
by the Examiner.

1 GROUND OF REJECTION TO BE REVIEWED

2 I. Rejection of Claims 1, 4, 5, 7-27 and 52-58 as being unpatentable under
3 35 U.S.C. § 103(a) over U.S. Patent No. 4,708,836 (Gain et al. - hereinafter referred to
4 as "Gain") in view of NPL#1, "Infant Skull Model and Sculpted Head" (Webb, Linda,
5 retrieved on Jun 09, 2002, retrieved from internet <URL:
6 http://web.archive.org/web/20020609002343/http://www.lindawebb.com/infant_s
7 [kull.htm](http://web.archive.org/web/20020609002343/http://www.lindawebb.com/infant_s)>, hereinafter referred to as "NPL#1") and further in view of
8 U.S. Patent No. 2003/0208 (Cecchi, hereinafter referred to as "Cecchi").

9 II. Rejection of Claims 14-17, 21-26 and 52-58 as being unpatentable under
10 35 U.S.C. § 103(a) over Gain in view of NPL#1, in view of U.S. Patent No. 5,609,485
11 (Bergman et al., hereinafter referred to as "Bergman") and further in view of Cecchi.

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1 cranium. Col. 5, ll. 42-60. Gain's FIG. 2 is entitled "A diagrammatic profile view of
2 a human head." Col. 4, ll. 64-65. FIG. 2 includes a fracture that is not identified by a
3 drawing element number. With respect to differences between the claims on appeal
4 and the cited art, Gain's specification does not disclose either the term "suture" or the
5 term "ultrasound." Gain's specification does not disclose how the different materials
6 would appear in an ultrasound model. Gain does not disclose how its artificial
7 cranium with its different materials would be relevant to ultrasound studies. Gain
8 discloses structural analysis equations in col. 6 and col. 7. A person of ordinary skill
9 in the art of Gain is someone with an engineering and testing background.

10 4. NPL#1 is entitled "Infant skull model and sculpted head." With respect
11 to scope, NPL # 1 discloses the creation of life-like sculptures. See EVIDENCE
12 SECTION, copy of <http://lindawebb.com/aboutlinda.htm>, and referred to in Office
13 Action Response dated 6/8/07, p. 18, ll. 10-11. With respect to content, NPL#1
14 discloses a model of an infant skull on the right side of the picture. It discloses a
15 sculpted head on the left side of the picture. NPL # 1 discloses that "Linda uses this
16 skull model to help her achieve the proper head shape of an infant." See EVIDENCE
17 SECTION, copy of http://lindawebb.com/infant_skull.htm, referred to in Office Action
18 Response dated 6/8/07, p. 18, ll. 12-13. NPL # 1 discloses that the artist specializes in
19 realistic, newborn sculptures. See EVIDENCE SECTION, copy of
20 <http://lindawebb.com/contents.htm>, referred to in Office Action Response dated 6/8/07,

1 p. 18, line 14. One of ordinary skill in the art of NPL#1 would be an artisan who
2 studies human anatomy in order to recreate life-like sculptures.

3 5. Cecchi is entitled "Embryo-Implanting Catheter Control System And
4 Method Of The Same." With respect to scope, it discloses an improved catheter
5 assembly, which is useful in performing embryo implants in a female's uterus.
6 Paragraph. 0013. With respect to content, a portion of the catheter assembly can be
7 tracked within the patient using ultrasound imaging equipment. Paragraph. 0048.
8 Cecchi discloses varying the density of an echogenic portion in order to be seen or to
9 be opaque, in images produced by ultrasonic imaging equipment. Paragraph. 0049.
10 With respect to differences between the claims on appeal and the cited art, Cecchi
11 does not disclose either manipulating density of materials in a training simulator or
12 how to manipulate the density of materials. Cecchi discloses a catheter assembly
13 (Claim 1), a method for forming an echogenic end of an instrument (Claim 15) and a
14 method for implanting an embryo (Claim 21). One of ordinary skill in the art would
15 be either an engineer with a biomedical engineering background or a surgeon or other
16 medical personnel.

17 6. Bergman is entitled "Medical Reproductive System." With respect to
18 scope, Bergman discloses a computer-based interactive system that reproduces a
19 medical examination by those using complex medical machinery, such as that used in
20 an ultrasound examination. Col. 1, ll. 6-10. It can be used as a diagnostic tool or as a

1 simulator for training purposes. Col. 1, ll. 13-15. With respect to content, Bergman
2 discloses that biological data are taken from a live patient and stored as ultrasound
3 images (col. 5, ll. 30-31) along with data relating to the position of the ultrasound
4 probe (col. 5, ll. 32-33). Using a simulated body and transmitter (col. 8, ll. 32-35), a
5 simulated ultrasound probe is provided that is held by a trainee and manipulated (col.
6 8, ll. 45-49). The simulated ultrasound probe contains a sensor (receiver) connected to
7 a simulated ultrasound unit. Col. 8, ll. 44-46. Signals received by the receiver in the
8 probe include position data. Col. 8, ll. 65-67. The position data are used by a
9 processor to reproduce a medical examination of the living body using the stored
10 biological display data. Col. 9, ll. 10-14. With respect to differences between the
11 claims on appeal and the cited art, Bergman displays previously collected ultrasound
12 images of the actual patient (Claim 1), because no ultrasound image is being collected
13 from the training session. Bergman does not disclose any opening in the simulated
14 body being modified between training sessions, in order to change an echogenicity.
15 Bergman discloses an ultrasound training system (Claim 1). One of ordinary skill in
16 the art would be either an engineer with a biomedical engineering background or a
17 physician or other medical personnel.

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1 ARGUMENT

2 Errors in Rejection Based on Gain in View of NPL#1 and Further in View of Cecchi

3 Claim 1

4 The Examiner erred in rejecting Claim 1 under 35 U.S.C. § 103(a) over the
5 cited art because a *prima facie* case of obviousness has not been established. There is
6 no motivation that would lead one of ordinary skill in the art of Cecchi to modify the
7 cited art to include at least one simulated patent skull suture. The cited art does not
8 teach or suggest including a second material that can be visually identified in an
9 ultrasound image and which prevents tactile detection during a training exercise.

10 The Examiner asserts that it would have been obvious to include the feature of
11 including simulated patent skull sutures, as seen in NPL#1, in the Gain system,
12 because it would enable the Gain system to better approximate the physiology of a
13 human infant. Office Action dated 10/28/2008, p. 4, first full paragraph. Appellants
14 have previously disagreed with the Examiner on this issue for the following reasons.

15 Gain does NOT emphasize that fine anatomical details (such as sutures)
16 are important in artificial craniums used for *mechanical tests for shock*
17 *resistance*. Gain notes that models suitable for the study of anatomy are
18 NOT suitable for mechanical crash studies. Gain indicates that what is
19 needed is an artificial cranium and a prosthetic head produced from same
20 cranium having the *same mechanical behavior and shape characteristics*
as a fresh cranium and a real head respectively” (column 1, ll. 61-65 –
emphasis added). Gain further explains that “shape characteristics”

1 means that the artificial cranium must have the same shape and
2 dimensions as a real human cranium and also include the cavities
3 corresponding to the natural cavities of a real human head (column 2,
4 ll. 7-12). Gain also emphasizes determining equivalent resin thickness so
5 that the compression strength at a given point of the artificial cranium is
6 equal to the compression strength at the corresponding point of the fresh
7 cranium (Gain, column 5, ll. 57-62). But, Gain then discloses that the
8 thickness of the material constituting the artificial cranium differs from
9 that of the real bone and that the internal cavities do not exactly
10 reproduce the cavities of the fresh cranium and indicates that these
11 dimensional differences are not important, so long as the mechanical
12 properties are faithfully replicated (Gain, column 5, ll. 18-23). Thus, the
13 approximate cranium mold 43, which comprises a lower part 54 and an
14 upper part 56, as seen in Gain's FIGURE 5, is used to produce the
15 artificial cranium that is sufficient for purposes of accident prevention
16 studies, and fine details of anatomical structures are ignored. Office
17 Action Response dated 1/22/2008, p. 12, ll. 11 – 28.

18 In other words, Gain does not teach or suggest that adding sutures to a
19 cranium used for crash studies would provide any benefit. Significantly,
20 there is simply no evidence indicating that sutures are at all relevant to
the studies being performed by Gain. Office Action Response dated
1/22/2008, p. 13, ll. 1-3.

In addition, the Examiner asserts that the Gain reference provides a teaching of
preventing tactile detection of a simulated patent skull sutures model, while enabling
the simulated patent skull to be visually detected based upon an appearance of the

1 simulated patent skull suture in an ultrasound image of said model as disclosed in col.
2 11:50-55 "skin." Office Action dated 10/28/2008, p. 4, first partial paragraph. The
3 Examiner further asserts that because the Cecchi reference provides a teaching of
4 modifying of lowering or increasing the density of the material to control the
5 echogenicity properties of the material, it would have been obvious to manipulate the
6 density of the second material. Office Action dated 10/28/2008, p. 4, second full
7 paragraph. The Examiner explains that doing so would enable the head model to have
8 the correct echogenic properties, as taught by Cecchi. *Id.* Appellants have previously
9 disagreed with the Examiner for the following reasons.

10 The "*correct echogenic properties*" remark by the Examiner is
11 significant. Only appellants, but none of the prior art references, define
12 what the *correct echogenic properties* of a head model should be.
13 Neither Gain nor NPL#1 require any particular *echogenic properties*.
14 Gain requires that the material properties of the model realistically
15 respond to mechanical stresses. The *echogenic properties* of the
16 materials are irrelevant in achieving this goal. Manipulating the
17 *echogenic properties* of the materials in Gain's model will not improve
18 the model with respect to its intended purpose, i.e., realistically
19 responding to mechanical stresses. Cecchi defines the *correct echogenic*
20 *properties* for an embryonic catheter, but not for a medical model for
training sonographers to detect craniosynostosis. The suggested
combination is impermissibly based on hindsight, because hindsight is
required to understand how the *correct echogenic properties* is important

1 in producing a head model, not the prior art. Amendment dated
2 1/28/2009, p. 15, ll. 1 – 10.

3 None of the cited art provides an equivalent to the specific structure
4 underlined above. Even if Cecchi's manipulation of materials was
5 included in a medical model, there would be no need for the second
6 material to extend beyond the opening. Amendment dated 1/28/2009,
p. 16, ll. 27 – 29.

6 Claim 21

7 Claim 21 has been rejected under 35 U.S.C. § 103(a), although no substantive
8 reasons are set forth. Office Action dated 10/28/2008, Item 7, p.3.

9 Appellants assert that Claim 21 is patentable for at least the following reasons.
10 First, there is no motivation to modify the cited art to include at least one simulated
11 patent skull suture. In addition, the cited art does not teach or suggest a hypoechoic
12 material that causes an echogenicity of the simulated skull suture to differ from that of
13 portions of the model not corresponding to the simulated patent skull suture. Also, the
14 cited art does not teach or suggest a filler material for selectively replacing the
15 hypoechoic material. Appellants have previously provided the following remarks to
16 explain why Claim 21 is patentable:

17 Gain discloses a model made of different materials for evaluating
18 mechanical stresses on the head during a crash (however, the different
19 materials are selected so that the model realistically responds to
20 mechanical stress, and the appearance of those materials in an ultrasound
image is not relevant to Gain's intended function, nor is there any

1 description in Gain as to how those materials used by Gain would appear
2 in an ultrasound image); NPL#1 discloses a model of an infant head
3 including patent skull sutures; and Cecchi discloses modifying a distal
4 portion of a catheter so that the distal portion can be more readily
5 observed in an ultrasound image. The Examiner's rejection appears to
6 assert that because Cecchi discloses that materials can be manipulated to
7 provide a desired appearance in an ultrasound image, it would have been
8 obvious to the artisan of ordinary skill to incorporate the patent skull
9 sutures of NPL#1 into Gain, using materials selected such that the patent
10 skull sutures are made of different materials than other portions of the
11 model, so that the patent skull sutures are visible in an ultrasound image.
12 Amendment dated 1/28/2009, p. 13, ll. 14-26.

11 Appellants respectfully disagree with this assertion for the following reasons.
12 The cited art (Gain, NPL#1, and Cecchi) provides no evidence that the
13 artisan of ordinary skill recognized that providing *a medical training*
14 *model that could be used to train sonographers to detect craniosynostosis*
15 represented a problem to be solved. While NPL#1 and Gain provide
16 models that can be used as visual aids for medical training, and Gain's
17 model is specifically constructed to realistically respond to the
18 application of mechanical stresses, those models are not designed to be
19 examined using ultrasound. It is appellants' position that applying
20 Cecchi's manipulation of materials to control what can be observed in an
ultrasound image to achieve a model for training sonographers to detect
craniosynostosis represents a combination that would not have been
obvious to the artisan of ordinary skill. Amendment dated 1/28/2009,

1 p. 13, line 28 - p. 14, line 6.

2 Claim 27

3 The Examiner erred in rejecting Claim 27 under 35 U.S.C. § 103(a) over the
4 cited art because a *prima facie* case of obviousness has not been established. The
5 cited art does not teach or suggest a model that includes at least one simulated patent
6 skull suture and does not teach or suggest at least one simulated fused skull suture. In
7 addition, the cited art does not teach or suggest that simulated patent skull sutures are
8 readily distinguishable from one another in an ultrasound image.

9 The Examiner asserts that it would have been obvious to include the feature of
10 simulated patent skull sutures, as seen in NPL#1, in the Gain system, because doing so
11 would enable the Gain system to better approximate the physiology of a human infant.
12 Office Action dated 10/28/2008, p. 4, first full paragraph. Appellants have previously
13 disagreed with the Examiner by stating that:

14 Claim 27 therefore distinguishes over the cited art for substantially the
15 same reasons as does Claim 1. Office Action Response dated 1/22/2008,
16 p. 14, ll. 8-9.

17 For the sake of brevity, these reasons are not repeated here. Please see the
18 arguments set forth above in traversing the rejection of Claim 1.

19 The Examiner has also cited to Gain's Figure 2 as providing a teaching of an
20 adult-looking skull model with a fused skull suture. Office Action dated 10/28/2008,
p. 19. The Examiner takes the position that it is common knowledge that different

1 skull bone in an adult human is characterized by fused skull sutures. *Id.* Appellants
2 have previously responded that they do NOT agree with the Examiner's assertion for
3 the following reasons.

4 The Examiner appears to have overlooked a recitation in Claim 27 that is
5 not taught or suggested by the cited references. Specifically, Claim 27
6 recites, "*a substantially life size model of a human head, said model*
7 *including at least one simulated patent skull suture and at least one*
8 *simulated fused skull suture, an echogenicity of each simulated patent*
9 *skull suture enabling the simulated patent skull suture to be readily*
10 *distinguishable from each simulated fused skull suture in an ultrasound*
11 *image of said model, such that each simulated patent skull suture will*
12 *appear dark in such an ultrasound image, and each simulated fused skull*
13 *suture will appear bright in such an ultrasound image.*" (Emphasis
14 added.) None of the references make any teaching or suggestion of
15 including a simulated fused skull suture in a model of a skull, which is
16 not surprising, since that condition is NOT considered a normal condition
17 in an infant's or child's skull. Accordingly, it is further not surprising
18 that none of the references teaches or suggests how such a simulated
19 fused skull suture on a model of a skull might be visually detected in an
20 ultrasound image of an ultrasound trainer, as recited in this claim. Office
Action Response dated 7/18/2008, p. 13, ll. 8-20.

Even if Gain were modified to include patent skull sutures because such
sutures represent fine anatomical detail that should be incorporated into a
model used for crash testing (and as discussed above appellants submit

1 that Gain *does not teach or suggest* that such fine anatomical details are
2 needed), note that fused skull sutures represent an abnormality. that
3 appears to have no relationship to the crash testing for which Gain's
4 models are to be used. There are many different anatomical
5 abnormalities possible in human heads, and Gain simply does not teach
6 or suggest that a head model used for crash test purposes should include
7 any such abnormality. To modify Gain's model to include *only* the
8 abnormality recited in appellants' claims, an abnormality having nothing
9 to do with crash testing, but which is very relevant to appellants'
10 ultrasound screening, appears to imperishably rely on hindsight. In other
11 words, there does not appear to be any reasonable rationale for modifying
12 Gain's model. Office Action Response dated 1/22/2008, p. 14, ll. 10-21.

13 Finally, no reference has been cited that teaches or suggests how simulated
14 skull sutures can be readily distinguished in an ultrasound image. Appellants have
15 previously pointed out to the Examiner that:

16 ..it is further not surprising that none of the references teach or suggest
17 how such a simulated fused skull suture on a model of a skull might be
18 visually detected in an ultrasound image of an ultrasound trainer. Office
19 Action Response dated 7/18/2008, p. 13, ll. 17-20.

20 Claim 52

The Examiner erred in rejecting Claim 52 under 35 U.S.C. § 103(a). Although
no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3),
appellants believe Claim 52 is patentable for at least the following reasons. There is
no motivation to modify the cited art to include at least one simulated patent skull

1 suture. The cited art does not teach or suggest a model that includes at least one
2 simulated patent skull suture that can be selectively modified to appear as a simulated
3 fused skull suture. The cited art does not teach or suggest how to modify a skull
4 suture such that the different simulated patent skull sutures can be readily
5 distinguished from non suture portions of the model in an ultrasound image. In the
6 interest of brevity, please see appellants' remarks directed to the traversal of the
7 rejection of Claim 52 under different grounds, as discussed below.

8 Claim 53

9 The Examiner erred in rejecting Claim 53 under 35 U.S.C. § 103(a) over the
10 cited art because a *prima facie* case of obviousness has not been established.
11 Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7,
12 p.3), appellants believe Claim 53 is patentable for at least the following reasons.
13 Again, there is no motivation to modify the cited art to include at least one simulated
14 patent skull suture. In addition, the cited art does not teach or suggest that the
15 simulated patent skull sutures can be reversibly modified. In the interest of brevity,
16 please see appellants' further remarks directed to the traversal of the rejection of
17 Claim 53 under different grounds, below.

18 Claim 54

19 The Examiner erred in rejecting Claim 54 under 35 U.S.C. § 103(a) over the
20 cited art because a *prima facie* case of obviousness has not been established.

1 Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7,
2 p.3), appellants believe Claim 54 is patentable for at least the following reasons. The
3 cited art does not teach or suggest either a simulated patent skull suture or a simulated
4 fused skull suture. In addition, the cited art does not teach or suggest a third material
5 that includes echogenic properties such that a simulated fused skull suture can be
6 distinguished from a simulated patent skull suture in an ultrasound image. In the
7 interest of brevity, please see appellants' further remarks directed to the traversal of
8 the rejection of Claim 54 under different grounds, below.

9 Claim 57

10 The Examiner erred in rejecting Claim 57 under 35 U.S.C. § 103(a) over the
11 cited art because a *prima facie* case of obviousness has not been established.
12 Although no substantive reasons are set forth (Office Action dated 10/28/2008, Item 7,
13 p.3), appellants believe Claim 57 is patentable for at least the following reasons. The
14 cited art does not teach or suggest at least one opening corresponding to a simulated
15 patent skull suture and at least one opening corresponding to a simulated fused skull
16 suture. In addition, the cited art does not teach or suggest a model being fabricated
17 from a first material and that a second material disposed within each opening
18 corresponding to a simulated patent skull suture will perform so that each opening
19 corresponding to the simulated patent skull suture can be distinguished from the first
20 material in an ultrasound. In addition, the cited art does not teach or suggest a third

1 material that includes echogenic properties such that at least one opening
2 corresponding to a simulated fused skull suture can be distinguished from a simulated
3 patent skull suture in an ultrasound image. In the interest of brevity, please see
4 appellants' further remarks directed to the traversal of the rejection of Claim 57 under
5 different grounds, below.

6 Claim 58

7 The Examiner erred in rejecting Claim 58 under 35 U.S.C. § 103(a) because a
8 *prima facie* case of obviousness has not been established. Although no substantive
9 reasons are set forth (Office Action dated 10/28/2008, Item 7, p.3), appellants believe
10 Claim 58 is patentable for at least the following reasons. The cited art does not teach
11 or suggest a plurality of openings each corresponding to a simulated patent skull
12 suture. The cited art does not teach or suggest a model including a filler material that
13 can be selectively added. In the interest of brevity, please see appellants' further
14 remarks directed to the traversal of the rejection of Claim 58 under different grounds,
15 below.

16 Errors in Rejection Based on Gain in View of NPL#1 in view of Bergman and Further
17 in View of Cecchi

18 Claim 21

19 The Examiner erred in rejecting Claim 21 under 35 U.S.C. § 103(a) over the
20 cited art because a *prima facie* case of obviousness has not been established. There is

1 no motivation to modify the cited art to include at least one simulated patent skull
2 suture. In addition, the cited art does not teach or suggest a hypoechoic material that
3 causes an echogenicity of the simulated skull suture to differ from that of portions of
4 the model not corresponding to the simulated patent skull suture. The cited art does
5 not teach or suggest a filler material for selectively replacing the hypoechoic material.

6 The Examiner asserts that it would have been obvious to include the feature of a
7 simulated patent skull suture, as seen in NPL#1, in the Gain system, because doing so
8 would enable the Gain system to better approximate the physiology of a human infant.
9 Office Action dated 10/28/2008, p. 11, first full paragraph. Appellants have
10 previously disagreed with the Examiner and stated that:

11 Claim 21 therefore distinguishes over the cited art for substantially the
12 same reasons as does Claim 1. Office Action Response dated 1/22/2008,
13 p. 13, ll. 11 – 12.

14 For the sake of brevity, these reasons are not being reproduced here. Instead,
15 please see the reasons given above in regard to appellants' traversal of the rejection of
16 Claim 1.

17 The Examiner asserts that the Cecchi reference provides a teaching of
18 modifying of lowering or increasing the density of the material to control the
19 echogenicity properties of the material. Office Action dated 10/28/2008, p. 11, second
20 full paragraph. The Examiner concludes that it would have been obvious to
manipulate the density of the second material because it would enable the head model

1 to have the correct echogenic properties, as taught by Cecchi. *Id.* Appellants have
2 previously disagreed with the Examiner on this point. In the interest of brevity, these
3 reasons are not now repeated. Instead, please see the remarks set forth above.

4 The Examiner also asserts that although Gain fails to provide a teaching that
5 reads on subparagraph (c), which provides for selectively modifying the model
6 between training sessions, Bergman provides this teaching in col. 8, ll. 35-50. Office
7 Action dated 10/28/2008, p. 11, last paragraph. – p. 12, first paragraph. The Examiner
8 concludes that it would have been obvious to do so in order to provide training in the
9 dynamic use of ultrasound on a simulated patient, having any one of a number of
10 desired training pathologies, as disclosed in Bergman at col. 2, ll. 1-5. *Id.* Appellants
11 have previously disagreed with the Examiner on this point because:

12 None of the art cited by the Examiner teaches or suggests filling an
13 opening in a model of a skull with a filler material that has an
14 echogenicity that is generally similar to that of the other portions of the
15 model, where the model can be modified between training sessions by
16 removing the filler material from at least one opening and adding the
17 filler material to a different opening. This approach is important so that a
18 student who has gone through one training session will not simply learn
19 where the fused skull suture is located on the model skull and be able to
20 use that knowledge to indicate where the fused skull suture is located in a
subsequent training session. By providing means to change the location
of the simulated fused skull suture between training sessions, the
usefulness of the model is greatly enhanced. This functionality is not

1 obvious in view of the art and is clearly supported in appellants'
2 specification at p. 16, line 25 Amendment dated 1/28/2009, p. 17,
3 line 22 – p. 18, line 1.

4 In addition, appellants have previously responded with the following argument.

5 Bergman discloses an ultrasound training model, based on a computer in
6 which are stored actual ultrasound images, a mannequin, and a sensor (a
7 position sensor capable of accurately determining the sensor's position
8 relative to the mannequin) that simulates an ultrasound probe. The
9 student moves the sensor relative to the mannequin, and based on the
10 sensor's position the computer displays a previously obtained ultrasound
11 image corresponding to the position of the sensor relative to the
12 mannequin. Note that no ultrasound image is actually being collected
13 during the training session; instead, previously collected ultrasound
14 images of actual humans (and not of the mannequin) are displayed.
15 Amendment dated 1/28/2009, p. 15, ll. 15-22.

16 With respect to "*selectively modifying a model between training*
17 *sessions*," the recorded ultrasound images presumably could be modified
18 between sessions (although it does not appear that Bergman discloses
19 such a modification), however, appellants cannot find any mention of an
20 opening in the mannequin being modified between sessions to change the
echogenicity of the opening. Further, such a modification would not be
logical, since the *echogenic properties* of the mannequin are irrelevant
for its intended use, because no actual ultrasound data is being collected
from the mannequin (only a relative position, so previously record

1 ultrasound images obtained from a real patient can be displayed).
2 Amendment dated 1/28/2009, p. 15, ll. 23-29.

3 The Examiner has specifically cited to 8:35-50 of Bergman as being
4 particularly relevant. Respectfully, that portion, reproduced below, does
5 not appear relevant to the pending claims, and *does not* disclose
6 “*selectively modifying a model between training sessions by enabling a
filler material to be added to an opening.*” Amendment dated 1/28/2009,
p.16, ll. 1-4.

7 Claim 52

8 The Examiner erred in rejecting Claim 52 because a *prima facie* case of
9 obviousness has not been established.. There is no motivation to modify the cited art
10 to include at least one simulated patent skull suture. The cited art does not teach or
11 suggest a model that includes at least one simulated patent skull suture that can be
12 selectively modified to appear as a simulated fused skull suture. The cited art does not
13 teach or suggest how to modify such that the different simulated patent skull sutures
14 can be readily distinguished from a non suture portion of the model in an ultrasound
15 image.

16 The Examiner asserts that it would have been obvious to include the feature of
17 having simulated patent skull sutures, as seen in NPL#1, in the Gain system, because
18 doing so would enable the Gain system to better approximate the physiology of a
19 human infant. Office Action dated 10/28/2008, p. 15, first paragraph.

20 Appellants have previously disagreed with the Examiner on this rejection, by

1 noting that “Claims 52 ... therefore distinguish over the cited art for substantially the
2 same reasons as does Claim 1.” Office Action Response dated 1/22/2008, p. 15, ll. 4-
3 5. For the sake of brevity, these reasons are not repeated here. Instead, please see the
4 remarks given above.

5 Furthermore, the Examiner asserts that although Gain does not teach that a skull
6 suture can be selectively modified, Bergman provides this teaching and cites to col. 8,
7 ll. 35-50. Office Action dated 10/28/2008, p. 15. The Examiner concludes that it
8 would have been obvious to include the feature of a skull suture that can be selectively
9 modified in order to provide any training in the dynamic use of ultrasound on a
10 simulated patient, having any one of a number of desired training pathologies as
11 disclosed in col. 2, ll. 1-5. *Id.* Appellants have previously disagreed with the
12 Examiner on this point for the following reasons.

13 The Bergman reference (U.S. Patent No. 5,609,485) **DOES NOT** disclose
14 *selectively modifying a model between training sessions by enabling a*
15 *filler material to be added to an opening.* Accordingly, the cited
16 combination of Bergman and Gain is not a valid rejection. Amendment
dated 1/28/2009, p. 19, ll. 7-11.

17 For the sake of brevity, the reasons will not be repeated. Instead, please see
18 above at page 27, line 9 through page 28, line 6.

19 Also, the Examiner asserts that although Gain is silent on echogenicity, the
20 difference in density of the first material epoxy resin and the second material – oil and

1 silicon mixture – would have resulted in a difference in echogenicity such that the
2 materials can be readily distinguished in an ultrasound image of said model. Office
3 Action dated 10/28/2008, p. 14. Appellants have previously disagreed with the
4 Examiner for the following reasons.

5 The prior art references ... do not in any way indicate how differences in
6 echogenicity between the simulated fused skull suture and the simulated
7 patent skull suture might be used to distinguish between the two in an
8 ultrasound image.” Office Action Response dated 7/18/2008, p. 14, ll. 2-
9 5).

10 In addition, appellants have previously noted:

11 The Examiner has asserted that the materials disclosed by Gain have
12 different echogenic properties and thus would be distinguishable in an
13 ultrasound image. The Examiner has not provided any evidentiary
14 support for this. Applicants are not disputing that materials have
15 echogenic properties, only that the materials disclosed by Gain would be
16 sufficient to enable simulated fused and patent skull sutures to be
17 differentiated. Some of the materials (the polymers) disclosed by Gain
18 are similar to materials disclosed by applicants for simulating a fused
19 skull suture (elastomers), however, Gain does not disclose any material
20 similar to the starch/glue mixture used to simulate the patent skull
sutures. Absent any actual evidence that the difference in echogenicity of
oil/silicone mixtures and epoxy resin is sufficient that such materials can
be used to generate a fused skull suture and a patent skull suture that can
be distinguished in an ultrasound image, this rejection is unwarranted.
Amendment dated 1/28/2009, p. 18, line 26 - p. 19, line 6.

1 Claim 53

2 The Examiner erred in rejecting Claim 53 under 35 U.S.C. § 103(a) over the
3 cited art because a *prima facie* case of obviousness has not been established. There is
4 no motivation to modify the cited art to include at least one simulated patent skull
5 suture. In addition, the cited art does not teach or suggest that the simulated patent
6 skull sutures can be reversibly modified.

7 The Examiner asserts that it would have been obvious to include the feature of
8 having simulated patent skull sutures as seen in NPL#1 in the Gain system, because it
9 would enable the Gain system to better approximate the physiology of a human infant.
10 Office Action dated 10/28/2008, p.16, first full paragraph. Appellants have
11 previously disagreed with the Examiner for the following reasons.

12 The Examiner again relies upon Gain and the first NPL reference for
13 teaching the recitation of Claim 53... it will now be apparent that the
14 claim recites a novel and non-obvious approach that is not taught or
15 suggested by the prior art references cited, since none of these references
16 even refer to including or detecting a simulated skull suture Office
17 Action Response dated 7/18/2008, p.14, ll. 15-17.

18 In addition, appellants have previously responded to explain why Gain does not
19 teach or suggest adding a suture to a model. However, for the sake of brevity, these
20 reasons are not being repeated here. Instead, please see the remarks above:

In addition, the Examiner asserts that although Gain does not teach that a skull

1 suture can be selectively modified, Bergman provides this teaching, and the Examiner
2 cites to col. 8, ll. 35-50. Office Action dated 10/28/2008, p. 16. The Examiner
3 concludes that it would have been obvious to include the feature of a skull suture that
4 can be selectively modified in order to provide any training in the dynamic use of
5 ultrasound on a simulated patient, having any one of a number of desired training
6 pathologies as disclosed in col. 2, ll. 1-5. Office Action dated 10/28/2008, pp. 16-17.

7 Appellants have previously disagreed with the Examiner on this point because
8 the cited references “do not discuss any manner in which a simulated patent skull
9 suture might be *reversibly* modified to produce a simulated fused skull suture.” Office
10 Action Response dated 7/18/2008, p. 14, ll. 16-17.

11 In addition, appellants have previously disagreed with the Examiner because
12 “as discussed above in detail, Bergman does not disclose that element.” Amendment
13 dated 1/28/2009, p.19, ll. 23. “That element” refers to the following discussion.

14 Bergman discloses an ultrasound training model, based on a computer in
15 which are stored actual ultrasound images, a mannequin, and a sensor (a
16 position sensor capable of accurately determining the sensor’s position
17 relative to the mannequin) that simulates an ultrasound probe. The
18 student moves the sensor relative to the mannequin, and based on the
19 sensor’s position the computer displays a previously obtained ultrasound
20 image corresponding to the position of the sensor relative to the
mannequin. Note that no ultrasound image is actually being collected
during the training session, rather previously collected ultrasound images

1 of actual humans (and not of the mannequin) are displayed. Amendment
2 dated 1/28/2009, p. 15, ll. 15-22.

3 With respect to *selectively modifying a model between training sessions*,
4 presumably the recorded ultrasound images could be modified between
5 sessions (although it does not appear that Bergman discloses such a
6 modification), however, applicants cannot find any mention of an
7 opening in the mannequin being modified between sessions to change the
8 echogenicity of the opening. Further, such a modification would not be
9 logical, as the *echogenic properties* of the mannequin are irrelevant, as
10 no actual ultrasound data is being collected from the mannequin (only a
relative position, so previously record ultrasound images obtained from a
real patient can be displayed). Amendment dated 1/28/2009, p. 15,
ll. 15-29.

11 Claim 54

12 The Examiner erred in rejecting Claim 54 under 35 U.S.C. § 103(a) over the
13 cited art because a *prima facie* case of obviousness has not been established. The
14 cited art does not teach or suggest either a simulated patent skull suture or a simulated
15 fused skull suture. In addition, the cited art does not teach or suggest a third material
16 that includes echogenic properties, such that a simulated fused skull suture can be
17 distinguished from a simulated patent skull suture in an ultrasound image.

18 The Examiner asserts that it would have been obvious to include the feature of
19 having simulated patent skull sutures, as seen in NPL#1, in the Gain system, because
20 doing so would enable the Gain system to better approximate the physiology of a

1 human infant. Office Action dated 10/28/2008, p. 17, second full paragraph.
2 Appellants have NOT previously disagreed with the Examiner on this point.
3 However, similar to their traversal set forth with respect to other independent claims
4 in the above-identified application, they do now disagree. For the sake of brevity,
5 these reasons are not being repeated here. Instead, please see the remarks above.

6 Further, no reference has been cited that teaches or suggests a fused simulated
7 patent skull suture, and appellants have previously responded that they do NOT agree
8 with the Examiner's rejection because:

9 None of the references teach a simulated fused skull suture Office
10 Action Response dated 7/18/2008, p. 14, ll. 29-30.

11 The Examiner also asserts that the Bergman reference provides a teaching of a
12 third material, at col. 8, ll.35-50. Office Action dated 10/28/2008, p. 18, last full
13 paragraph. The Examiner concludes that the recitation in appellants' paragraph (b) of
14 Claim 54, regarding the third material being disposed within each opening
15 corresponding to a simulated fused skull suture wherein the echogenicity of the third
16 material is distinguishable from the echogenicity of the second material in order for
17 each simulated fused skull suture to be distinguished from each simulated patent skull
18 suture in an ultrasound image, is obvious in view of Bergman. *Id.* He reaches this
19 conclusion because Bergman teaches selectively modifying the model, with the
20 motivation being to provide training on a simulated patient. *Id.* Appellants have

1 previously disagreed with the Examiner on this point, because:

2 None of the references ...teach or suggest that a third material disposed
3 in an opening in a model of a skull is used for a simulated fused skull
4 suture. There is also no teaching or suggestion that the third material
5 disposed in an opening of a model of a skull might have an echogenicity
6 that is readily distinguished from an echogenicity of a second material
7 used in the simulated patent skull sutures, so that the simulated fused
8 skull suture can be readily distinguished from each simulated patent skull
suture in an ultrasound image of the model. Office Action Response
dated 7/18/2008, p. 14, line 29-p. 15, line 5.

9 Claim 57

10 The Examiner erred in rejecting Claim 57 under 35 U.S.C. § 103(a) over the
11 cited art because a *prima facie* case of obviousness has not been established. The
12 cited art does not teach or suggest at least one opening corresponding to simulated
13 patent skull suture and at least one opening corresponding to a simulated fused skull
14 suture. In addition, the cited art does not teach or suggest a model being fabricated
15 from a first material, or that a second material disposed within each opening
16 corresponding to a simulated patent skull suture will perform so that each opening
17 corresponding to the simulated patent skull suture can be distinguished from the first
18 material in an ultrasound image. In addition, the cited art does not teach or suggest a
19 third material that includes echogenic properties such that at least one opening
20 corresponding to a simulated fused skull suture can be distinguished from a simulated

1 patent skull suture in an ultrasound image.

2 The Examiner asserts that it would have been obvious to include the feature of
3 having simulated patent skull sutures, as seen in NPL#1, in the Gain system, because
4 it would enable the Gain system to better approximate the physiology of a human
5 infant. Office Action dated 10/28/2008, p. 17, second full paragraph. Appellants have
6 NOT previously noted that they disagree with the Examiner on this point. However,
7 for reasons similar to their traversal set forth with respect to other independent claims
8 in the above-identified application, they do indeed disagree. These remarks are not
9 being repeated here for the sake of brevity. Instead, please see the remarks above.

10 No reference has been cited that teaches or suggests a fused simulated patent
11 skull suture. Appellants have previously responded that they do NOT agree with the
12 Examiner, because "None of the references teach a simulated fused skull suture"
13 Office Action Response dated 7/18/2008, p. 14, ll. 29-30.

14 In addition, the Examiner asserts that the Bergman reference provides a
15 teaching of a third material in col. 8, ll.35-50. Office Action dated 10/28/2008, p. 18,
16 last full paragraph. The Examiner concludes that the recitation in appellants'
17 paragraph (b) of Claim 57, regarding the third material being disposed within each
18 opening corresponding to a simulated fused skull suture wherein the echogenicity of
19 the third material is distinguishable from the echogenicity of the second material in
20 order for each simulated fused skull suture to be distinguished from each simulated

1 patent skull suture in an ultrasound image, is obvious in view of Bergman. *Id.* He
2 justifies this assertion by stating that Bergman teaches selectively modifying the
3 model, with the motivation being to provide training on a simulated patient. *Id.*
4 Appellants have previously disagreed on this point with the Examiner. These reasons
5 will not be repeated for the sake of brevity, please see above, page 35, lines 7-13.

6 Claim 58

7 Claim 58 has been rejected under 35 U.S.C. § 103(a), although no substantive
8 reasons are set forth. Office Action dated 10/28/2008, Item #8, p. 9. Again, there is
9 no motivation to modify the cited art to include at least one simulated patent skull
10 suture. In the interest of brevity, please see the reasons set forth above. In addition,
11 there are no references cited that disclose selectively adding a filler material to at least
12 one opening, in order to create a simulated fused skull suture.

13 For at least the reasons set forth above, appellants respectfully request that the
14 Board of Patent Appeals and Interferences overrule the Examiner's rejection of all of
15 the claims. The patentability of each dependent claim is not necessarily separately
16 addressed in detail. However, appellants' decision NOT to discuss the differences
17 between the cited art and each dependent claim should not be considered as an
18 admission that appellants concur with the Examiner's conclusion that these dependent
19 claims are not patentable over the disclosure in the cited references. Similarly,
20 appellants' decision not to discuss differences between the prior art and every claim

1 element, or every comment made by the Examiner, should not be considered as an
2 admission that appellants concur with the Examiner's interpretation and assertions
3 regarding those claims. Indeed, appellants believe that all of the dependent claims
4 patentably distinguish over the references cited. In any event, a specific traverse of the
5 rejection of each dependent claim is not required, since dependent claims are patentable
6 for at least the same reasons as the independent claims from which the dependent
7 claims ultimately depend. Because dependent claims inherently include each element
8 recited in the independent claim upon which they ultimately depend, each claim
9 depending upon its respective independent claim is patentable for at least the same
10 reasons as those discussed above. Accordingly, appellants respectfully request that
11 the Board of Patent Appeals and Interferences overrule the Examiner's rejection of all
12 of the dependent claims as well as of the independent claims.

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1 APPENDIX

2 CLAIMS SECTION

3 1. (Rejected) A medical simulator for training ultrasound operators to perform
4 craniosynostosis screenings using medical ultrasound, comprising a substantially life
5 size model of a human infant head, said model being at least in part fabricated from a
6 first material, said model including at least one simulated patent skull suture
7 comprising a second material and a scalp portion in which each simulated patent skull
8 suture is disposed, such that the scalp portion of the model is covered with a layer of
9 the second material, the second material extending beyond an opening in the first
10 material defining the simulated patent skull suture and covering at least a portion of
11 the first material, to prevent the simulated patent skull suture from being identified
12 tactilely, the second material having an echogenicity substantially different than an
13 echogenicity of said first material, such that each simulated patent skull suture can be
14 readily distinguished in an ultrasound image of said model.

15 2. (Canceled)

16 3. (Canceled)

17 4. (Rejected) The medical simulator of Claim 1, wherein the second material is
18 hypoechoic relative to the first material.

19 5. (Rejected) The medical simulator of Claim 1, wherein the echogenicity of
20 the second material is lower than the echogenicity of the first material, such that in an

1 ultrasound image of the model, portions of the model corresponding to the first
2 material appear relatively bright and portions of the model corresponding to the
3 second material appear relatively dark.

4 6. (Canceled)

5 7. (Rejected) The medical simulator of Claim 1, wherein the second material
6 comprises a mixture of a starch and a glue.

7 8. (Rejected) The medical simulator of Claim 7, wherein the glue is a casein-
8 based glue.

9 9. (Rejected) The medical simulator of Claim 7, wherein the glue is a synthetic
10 resin-based glue.

11 10. (Rejected) The medical simulator of Claim 1, wherein at least one
12 simulated patent skull suture corresponds to at least one of a simulated patent coronal
13 skull suture and a simulated patent lambdoid skull suture, and wherein each opening
14 corresponding to a simulated patent coronal skull suture is beveled, and each opening
15 corresponding to a simulated patent lambdoid skull suture is beveled.

16 11. (Rejected) The medical simulator of Claim 1, wherein at least one opening
17 corresponding to a simulated patent skull suture corresponds to at least one of a
18 simulated patent sagittal skull suture and a simulated patent metopic skull suture, so
19 that opposed walls of each opening corresponding to a simulated patent sagittal skull
20 suture exhibit an end-to-end configuration, and opposed walls of each opening

1 corresponding to a simulated patent metopic skull suture exhibit an end-to-end
2 configuration.

3 12. (Rejected) The medical simulator of Claim 1, further comprising at least
4 one simulated fused skull suture.

5 13. (Rejected) The medical simulator of Claim 12, wherein each simulated
6 fused skull suture comprises said first material.

7 14. (Rejected) The medical simulator of Claim 12, wherein each simulated fused
8 skull suture comprises an opening within said first material, each opening corresponding
9 to a simulated fused skull structure in which a third material is disposed, an echogenicity
10 of the third material being substantially distinguishable from the echogenicity of the
11 second material, so that each opening corresponding to a simulated fused skull suture can
12 be readily distinguished from an opening corresponding to a simulated patent skull suture
13 in an ultrasound image of said model.

14 15. (Rejected) The medical simulator of Claim 14, wherein the echogenicity of
15 the third material is substantially similar to the echogenicity of the first material, such
16 that in an ultrasound image of the model, portions of the model comprising the first
17 material are not readily distinguishable from portions of the model comprising the
18 third material.

19 16. (Rejected) The medical simulator of Claim 14, wherein the third material
20 comprises a synthetic elastomer.

1 17. (Rejected) The medical simulator of Claim 16, wherein the synthetic
2 elastomer comprises dimethyl siloxane, hydroxy-terminated polymers, and silica.

3 18. (Rejected) The medical simulator of Claim 12, further comprising an
4 opaque layer configured to cover each simulated patent skull suture and each
5 simulated fused skull suture, so that a trainee cannot readily visually determine
6 whether a specific skull suture is patent or fused by visually inspecting the model.

7 19. (Rejected) The medical simulator of Claim 1, further comprising an
8 opaque layer configured to cover a scalp portion of the model, so that a trainee cannot
9 readily visually locate each simulated patent skull suture by visually inspecting the
10 model.

11 20. (Rejected) The medical simulator of Claim 1, wherein a doll's head is
12 utilized for the substantially life size model of a human head.

13 21. (Rejected) A medical simulator adapted to be used to train ultrasound
14 operators to perform craniosynostosis screenings using medical ultrasound,
15 comprising:

16 (a) a substantially life size model of a human infant head, said model
17 including a plurality of openings;

18 (b) a solid or semi-solid hypoechoic material being included in each
19 opening so that the opening corresponds to a simulated patent skull suture, wherein
20 the hypoechoic material causes an echogenicity of the simulated skull suture to differ

1 from that of portions of the model not corresponding to the simulated patent skull
2 suture, the difference enabling each simulated patent skull suture to be identified in an
3 ultrasonic image; and

4 (c) a filler material for selectively replacing the hypoechoic material
5 included in at least one selected opening, the filler material having an echogenicity
6 that is generally similar to that of the portions of the model not corresponding to the
7 simulated skull suture, so that each opening in which the filler material replaces the
8 hypoechoic material simulates a fused skull suture in an ultrasonic image, the model
9 being modifiable between training sessions by replacing the hypoechoic material with
10 the filler material in at least one opening.

11 22. (Rejected) The medical simulator of Claim 21, wherein when the medical
12 simulator is imaged using ultrasound, the hypoechoic material produces a relatively
13 dark image, whereas adjacent portions of the model produce a relatively bright image,
14 such that each simulated patent skull suture appears in the ultrasound image as a
15 relatively dark area surrounded by relatively brighter areas.

16 23. (Rejected) The medical simulator of Claim 21, wherein said model is
17 fabricated from a first material, such that the solid or semi-solid hypoechoic material
18 included in each opening corresponding to a simulated patent skull suture represents a
19 second material, an echogenicity of the second material being substantially different
20 than the echogenicity of the first material, so that each opening corresponding to a

1 simulated patent skull suture can be readily distinguished from the first material in an
2 ultrasound image of said model.

3 24. (Rejected) The medical simulator of Claim 23, wherein the echogenicity of
4 the second material is lower than the echogenicity of the first material, such that in an
5 ultrasound image of the model, portions of the model comprising the first material
6 will appear relatively bright, while portions of the model comprising the second
7 material will appear relatively dark.

8 25. (Rejected) The medical simulator of Claim 23, wherein the filler material
9 for simulating a fused skull suture comprises a third material, an echogenicity of the
10 third material being substantially different than the echogenicity of the second
11 material, so that each opening corresponding to a simulated fused skull suture can be
12 readily distinguished from an opening corresponding to a simulated patent skull suture
13 in an ultrasound image of said model.

14 26. (Rejected) The medical simulator of Claim 21, wherein:

15 (a) each opening corresponding to a simulated patent skull suture
16 intended to represent a patent coronal skull suture is beveled;

17 (b) each opening corresponding to a simulated patent skull suture
18 intended to represent a patent lambdoid skull suture is beveled;

19 (c) each opening corresponding to a simulated patent skull suture
20 intended to represent a patent sagittal skull suture is disposed such that opposed walls

1 of the opening exhibit an end-to-end configuration; and

2 (d) each opening corresponding to a simulated patent skull suture
3 intended to represent a patent metopic skull suture is disposed such that opposed walls
4 of the opening exhibit an end-to-end configuration.

5 27. (Rejected) An ultrasound trainer configured to train ultrasound operators to
6 perform craniosynostosis screenings using medical ultrasound; comprising a
7 substantially life size model of a human infant head, said model including at least one
8 simulated patent skull suture and at least one simulated fused skull suture, an
9 echogenicity of each simulated patent skull suture enabling the simulated patent skull
10 suture to be readily distinguishable from each simulated fused skull suture in an
11 ultrasound image of said model, such that each simulated patent skull suture will
12 appear dark in such an ultrasound image, and each simulated fused skull suture will
13 appear bright in such an ultrasound image.

14 28.-51. (Canceled)

15 52. (Rejected) A medical simulator for training ultrasound operators to
16 perform craniosynostosis screenings using medical ultrasound, comprising a
17 substantially life-size model of a human infant head, said model including two eyes, a
18 mouth, two ears, and at least one simulated patent skull suture that can be selectively
19 modified to appear as a simulated fused skull suture, a difference in echogenicity of
20 each simulated patent skull suture and each simulated fused skull suture enabling each

1 simulated patent skull suture to be readily distinguishable from non suture portions of
2 the model and from each simulated fused suture in an ultrasound image of said model.

3 53. (Rejected) A medical simulator for training ultrasound operators to
4 perform craniosynostosis screenings using medical ultrasound, comprising a
5 substantially life size model of a human head, said model including a plurality of
6 simulated patent skull sutures, an echogenicity of each simulated patent skull suture
7 enabling the simulated patent skull suture to be readily distinguishable in an
8 ultrasound image of said model, such that each simulated patent skull suture will
9 appear dark in such an ultrasound image, whereas adjacent portions of said model will
10 appear bright in such an ultrasound image; and, further comprising means for
11 reversibly modifying one or more selected simulated patent skull sutures to create one
12 or more simulated fused skull sutures that can readily be detected in an ultrasound
13 image, wherein each simulated fused skull suture will appear bright in the ultrasound
14 image, like the portions of the model that are adjacent to the simulated patent skull
15 sutures.

16 54. (Rejected) A medical simulator for training ultrasound operators to
17 perform craniosynostosis screenings using medical ultrasound, comprising a
18 substantially life size model of a human head, said model being at least in part
19 fabricated from a first material, said model including:
20

1 (a) at least one simulated patent skull suture being at least in part
2 fabricated from a second material, said second material comprising at least one of a
3 solid and a semi-solid, an echogenicity of said second material being substantially
4 different than an echogenicity of said first material, such that each simulated patent
5 skull suture can be readily distinguished in an ultrasound image of said model; and

6 (b) at least one simulated fused skull suture, wherein each simulated
7 fused skull suture comprises an opening within said first material, a third material
8 being disposed within each opening corresponding to a simulated fused skull
9 structure, an echogenicity of the third material being substantially distinguishable
10 from the echogenicity of the second material, so that each simulated fused skull suture
11 can be readily distinguished from each simulated patent skull suture in an ultrasound
12 image of said model.

13 55. (Rejected) The medical simulator of Claim 54, wherein the echogenicity of
14 the third material is substantially similar to the echogenicity of the first material, such
15 that in an ultrasound image of the model, portions of the model comprising the first
16 material are not readily distinguishable from portions of the model comprising the
17 third material.

18 56. (Rejected) The medical simulator of Claim 54, wherein the third material
19 comprises a synthetic elastomer.
20

1 57. (Rejected) A medical simulator adapted to be used to train ultrasound
2 operators to perform craniosynostosis screenings using medical ultrasound,
3 comprising:

4 (a) a substantially life size model of a human head, said model
5 including at least one opening corresponding to a simulated patent skull suture, a solid
6 or semi-solid hypoechoic material being disposed within each such opening to
7 enhance a difference in an echogenicity of the simulated skull suture relative to that of
8 portions of the model not corresponding to the simulated patent skull suture, the
9 difference enabling each simulated patent skull suture to be identified in an ultrasonic
10 image, said model being fabricated from a first material, such that the solid or semi-
11 solid hypoechoic material disposed within each opening corresponding to a simulated
12 patent skull suture represents a second material, an echogenicity of the second
13 material being substantially different than the echogenicity of the first material, so that
14 each opening corresponding to a simulated patent skull suture can be readily
15 distinguished from the first material in an ultrasound image of said model; and

16 (b) at least one opening corresponding to a simulated fused skull
17 suture, a third material being disposed within each opening corresponding to a
18 simulated fused skull suture, an echogenicity of the third material being substantially
19 different than the echogenicity of the second material, so that each opening
20 corresponding to a simulated fused skull suture can be readily distinguished from an

1 opening corresponding to a simulated patent skull suture in an ultrasound image of
2 said model.

3 58. (Rejected) A medical simulator adapted to be used to train ultrasound
4 operators to perform craniosynostosis screenings using medical ultrasound,
5 comprising:

6 (a) a substantially life size model of an infant head, said model
7 including a plurality of openings each corresponding to a simulated patent skull
8 suture, a hypoechoic material being disposed within the opening to enhance a
9 difference in an echogenicity of the simulated skull suture relative to that of portions
10 of the model not corresponding to the simulated patent skull suture, the difference
11 enabling each simulated patent skull suture to be identified in an ultrasonic image; and

12 (b) a first filler material that can be selectively added to at least one of
13 the plurality of openings by a user, said first filler material having an echogenicity
14 about equal to that of the portions of the model not corresponding to a simulated
15 patent skull suture, such that when the first filler material is added to at least one
16 opening, the first filler material in the opening creates a simulated fused skull suture.

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1 CLAIMS SUPPORT AND DRAWING ANALYSIS SECTION

2 1. (Rejected) A medical simulator for training ultrasound operators to perform
3 craniostosis screenings using medical ultrasound, comprising a substantially life
4 size model {Fig. 1A, element 10; paragraph 0041} of a human infant head, said model
5 being at least in part fabricated from a first material {plastic material of paragraph
6 0045, ll. 1-2}, said model including at least one simulated patent skull suture {Fig.
7 1A, element 12; paragraph 0041} comprising a second material {GOOOZE™ or
8 mixture of starch and glue; paragraph 0045, ll. 11-14} and a scalp portion in which
9 each simulated patent skull suture is disposed, such that the scalp portion of the model
10 is covered with a layer of the second material {paragraph 0078, ll. 14-17}, the second
11 material extending beyond an opening {paragraph 0025} in the first material defining
12 the simulated patent skull suture and covering at least a portion of the first material, to
13 prevent the simulated patent skull suture from being identified tactilely {paragraph
14 0052, ll. 5-8}, the second material having an echogenicity substantially different than
15 an echogenicity of said first material {paragraph 0050, ll. 3-4}, such that each
16 simulated patent skull suture can be readily distinguished in an ultrasound image of
17 said model {paragraph 0050, ll. 12-13, paragraph 0015, ll. 1-3}.

18 21. (Rejected) A medical simulator adapted to be used to train ultrasound
19 operators to perform craniostosis screenings using medical ultrasound,
20 comprising:

1 (a) a substantially life size model. {Fig. 1A, element 10; paragraph
2 0041} of a human infant head, said model including a plurality of openings
3 {paragraph 0025};

4 (b) a solid or semi-solid hypoechoic material {GOOOZE™ or mixture
5 of starch and glue; paragraph 0045, ll. 11-14; paragraph 0051, ll. 16-18} being
6 included in each opening so that the opening corresponds to a simulated patent skull
7 suture {Fig. 1A, element 12; paragraph 0041}, wherein the hypoechoic material
8 causes an echogenicity of the simulated skull suture to differ from that of portions of
9 the model not corresponding to the simulated patent skull suture {paragraph 0051,
10 ll. 10-15}, the difference enabling each simulated patent skull suture to be identified
11 in an ultrasonic image {paragraph 0051, ll. 19-24}; and

12 (c) a filler material {synthetic moldable polymer; paragraph 0058} for
13 selectively replacing {paragraph 0057, line 13} the hypoechoic material included in at
14 least one selected opening, the filler material having an echogenicity that is generally
15 similar to that of the portions of the model not corresponding to the simulated skull
16 suture {paragraph 0055, ll. 16-22}, so that each opening in which the filler material
17 replaces the hypoechoic material simulates a fused skull suture {paragraph 0055,
18 ll. 16-22} in an ultrasonic image, the model being modifiable between training
19 sessions by replacing the hypoechoic material with the filler material in at least one
20 opening {paragraph 0057, ll. 17-21}.

1 27. (Rejected) An ultrasound trainer configured to train ultrasound operators to
2 perform craniosynostosis screenings using medical ultrasound; comprising a
3 substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human infant
4 head, said model including at least one simulated patent skull suture {Fig. 1A,
5 element 12; paragraph 0041} and at least one simulated fused skull suture {paragraph
6 0055, ll. 16-20}, an echogenicity of each simulated patent skull suture enabling the
7 simulated patent skull suture to be readily distinguishable from each simulated fused
8 skull suture in an ultrasound image of said model {paragraph 0055, ll. 16-22}, such
9 that each simulated patent skull suture will appear dark {paragraph 0071, ll. 6-7} in
10 such an ultrasound image, and each simulated fused skull suture will appear bright in
11 such an ultrasound image {paragraph 0055, ll. 22-26}.

12 52. (Rejected) A medical simulator for training ultrasound operators to
13 perform craniosynostosis screenings using medical ultrasound, comprising a
14 substantially life-size model {Fig. 1A, element 10; paragraph 0041} of a human infant
15 head, said model including two eyes, a mouth, two ears {paragraph 0068}, and at least
16 one simulated patent skull suture {Fig. 1A, element 12; paragraph 0041} that can be
17 selectively modified to appear as a simulated fused skull suture {paragraph 0057,
18 ll. 11-16}, a difference in echogenicity of each simulated patent skull suture and each
19 simulated fused skull suture enabling each simulated patent skull suture to be readily
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1 distinguishable from non suture portions of the model and from each simulated fused
2 suture in an ultrasound image of said model {paragraph 0055, ll. 16-22}.

3 53. (Please refer to the means plus function analysis section for this claim)

4 54. (Rejected) A medical simulator for training ultrasound operators to
5 perform craniosynostosis screenings using medical ultrasound, comprising a
6 substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human head,
7 said model being at least in part fabricated from a first material {plastic material of
8 paragraph 0045, ll. 1-2}, said model including:

9 (a) at least one simulated patent skull suture {Fig. 1A, element 12;
10 paragraph 0041} being at least in part fabricated from a second material {GOOOZE™
11 or mixture of starch and glue; paragraph 0045, ll. 11-14}, said second material
12 comprising at least one of a solid and a semi-solid, an echogenicity of said second
13 material being substantially different than an echogenicity of said first material
14 {paragraph 0050, ll. 3-4}, such that each simulated patent skull suture can be readily
15 distinguished in an ultrasound image of said model {paragraph 0050, ll. 12-13,
16 paragraph 0015, ll. 1-3}; and

17 (b) at least one simulated fused skull suture {paragraph 0055, ll. 16-
18 22}, wherein each simulated fused skull suture comprises an opening {paragraph
19 0025} within said first material, a third material {SILLY PUTTY™, paragraph 0058}
20 being disposed within each opening corresponding to a simulated fused skull

1 structure, an echogenicity of the third material being substantially distinguishable
2 from the echogenicity of the second material {paragraph.0066, ll. 1-4}, so that each
3 simulated fused skull suture can be readily distinguished from each simulated patent
4 skull suture in an ultrasound image of said model {paragraph.0066, ll. 4-6}.

5 57. (Rejected) A medical simulator adapted to be used to train ultrasound
6 operators to perform craniosynostosis screenings using medical ultrasound,
7 comprising:

8 (a) a substantially life size model {Fig. 1A, element 10; paragraph
9 0041} of a human head, said model including at least one opening {paragraph 0025}
10 corresponding to a simulated patent skull suture {Fig. 1A, element 12; paragraph
11 0041}, a solid or semi-solid hypoechoic material {GOOOZE™ or mixture of starch
12 and glue; paragraph 0045, ll. 11-14; paragraph 0051, ll. 16-18} being disposed within
13 each such opening to enhance a difference in an echogenicity of the simulated skull
14 suture relative to that of portions of the model not corresponding to the simulated
15 patent skull suture {paragraph 0051, ll. 10-15}, the difference enabling each simulated
16 patent skull suture to be identified in an ultrasonic image {paragraph 0051, ll. 19-24},
17 said model being fabricated from a first material {plastic material of paragraph 0045,
18 ll. 1-2}, such that the solid or semi-solid hypoechoic material disposed within each
19 opening corresponding to a simulated patent skull suture represents a second material
20 {GOOOZE™ or mixture of starch and glue; paragraph 0045, ll. 11-14}, an

1 echogenicity of the second material being substantially different than the echogenicity
2 of the first material {paragraph 0050, ll. 3-4}, so that each opening corresponding to a
3 simulated patent skull suture can be readily distinguished from the first material in an
4 ultrasound image of said model {paragraph 0050, ll. 12-13, paragraph 0015, ll. 1-3};
5 and

6 (b) at least one opening corresponding to a simulated fused skull
7 suture {paragraph 0055, ll. 16-22}, a third material {SILLY PUTTY™, paragraph
8 0058} being disposed within each opening corresponding to a simulated fused skull
9 suture, an echogenicity of the third material being substantially different than the
10 echogenicity of the second material {paragraph.0066, ll. 1-4}, so that each opening
11 corresponding to a simulated fused skull suture can be readily distinguished from an
12 opening corresponding to a simulated patent skull suture in an ultrasound image of
13 said model {paragraph.0066, ll. 4-6}.

14 58. (Rejected) A medical simulator adapted to be used to train ultrasound
15 operators to perform craniosynostosis screenings using medical ultrasound,
16 comprising:

17 (a) a substantially life size model {Fig. 1A, element 10; paragraph
18 0041} of an infant head, said model including a plurality of openings each
19 corresponding to a simulated patent skull suture {Fig. 1A, element 12; paragraph
20 0041}, a hypoechoic material being disposed within the opening to enhance a

1 difference in an echogenicity of the simulated skull suture relative to that of portions
2 of the model not corresponding to the simulated patent skull suture {paragraph 0051,
3 ll. 10-15}, the difference enabling each simulated patent skull suture to be identified
4 in an ultrasonic image {paragraph 0051, ll. 19-24}; and

5 (b) a first filler material {synthetic moldable polymer; paragraph
6 0058} that can be selectively added to at least one of the plurality of openings by a
7 user, said first filler material having an echogenicity about equal {paragraph 0056,
8 ll. 1-4} to that of the portions of the model not corresponding to a simulated patent
9 skull suture {Fig. 1A, element 12; paragraph 0041}, such that when the first filler
10 material is added to at least one opening, the first filler material in the opening creates
11 a simulated fused skull suture {paragraph 0056, ll. 4-9}:

1 MEANS PLUS FUNCTION ANALYSIS SECTION

2 53. (Rejected) A medical simulator for training ultrasound operators to
3 perform craniosynostosis screenings using medical ultrasound, comprising a
4 substantially life size model {Fig. 1A, element 10; paragraph 0041} of a human head,
5 said model including a plurality of simulated patent skull sutures {Fig. 1A,
6 element 12; paragraph 0041}, an echogenicity of each simulated patent skull suture
7 enabling the simulated patent skull suture to be readily distinguishable in an
8 ultrasound image of said model {paragraph 0055, ll. 16-22}, such that each simulated
9 patent skull suture will appear dark {paragraph 0071, ll. 6-7} in such an ultrasound
10 image, whereas adjacent portions of said model will appear bright in such an
11 ultrasound image {paragraph 0051, ll. 11-13}; and, further comprising means for
12 reversibly modifying {"...removing the simulated patent skull suture fill material
13 from one or more openings and replacing that material with the simulated fused
14 skull suture fill material", paragraph 0057, ll. 14-17; or "...cover can simply be
15 placed over the simulated patent skull suture fill material and the ultrasonic
16 image would indicate that particular simulated skull suture was fused",
17 paragraph 0067, ll. 4-13} one or more selected simulated patent skull sutures to
18 create one or more simulated fused skull sutures that can readily be detected in an
19 ultrasound image, wherein each simulated fused skull suture will appear bright in the
20 ultrasound image, like the portions of the model that are adjacent to the simulated

1 patent skull sutures {paragraph 0055, ll. 22-25}.

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1 EVIDENCE SECTION

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1 <http://lindawebb.com/aboutlinda.htm>




2 LW Art Originals - About Linda Webb

3 The desire to create life-like infants came after
4 the birth of my son, Benjamin in 1978. I knew
5 photographs and memories would not be enough
6 to hold the image in my heart. Learning infant
7 anatomy will be an on going study for years to
8 come. My desire to create realism has taken me
9 to nurseries, hospitals, and museums. I have
10 made special friends along the way with doctors,
11 collectors, and the parents of newborns.

I want to thank everyone who has been such an
important part of making my dolls come to life.

With love, peace and kindness always,


Please email questions or comments to:
LWAtoLindaWebb.com
Due to the large volume of email we receive, please
allow several days for a response. Thank you.

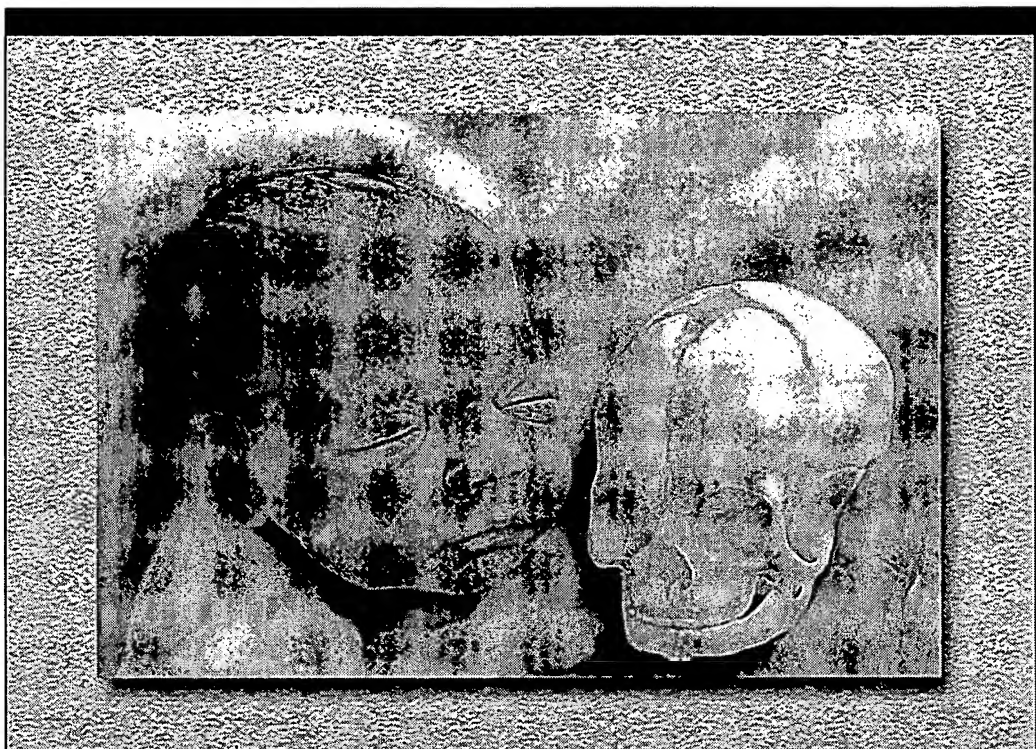



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18 <http://lindawebb.com/aboutlinda.htm> 2/10/2009 1:26:22 PM

1 http://lindawebb.com/infant_skull.htm

2 Infant Skull



11 Infant skull model and sculpted head.

12 Linda uses this model to help her achieve the proper head shape of an infant

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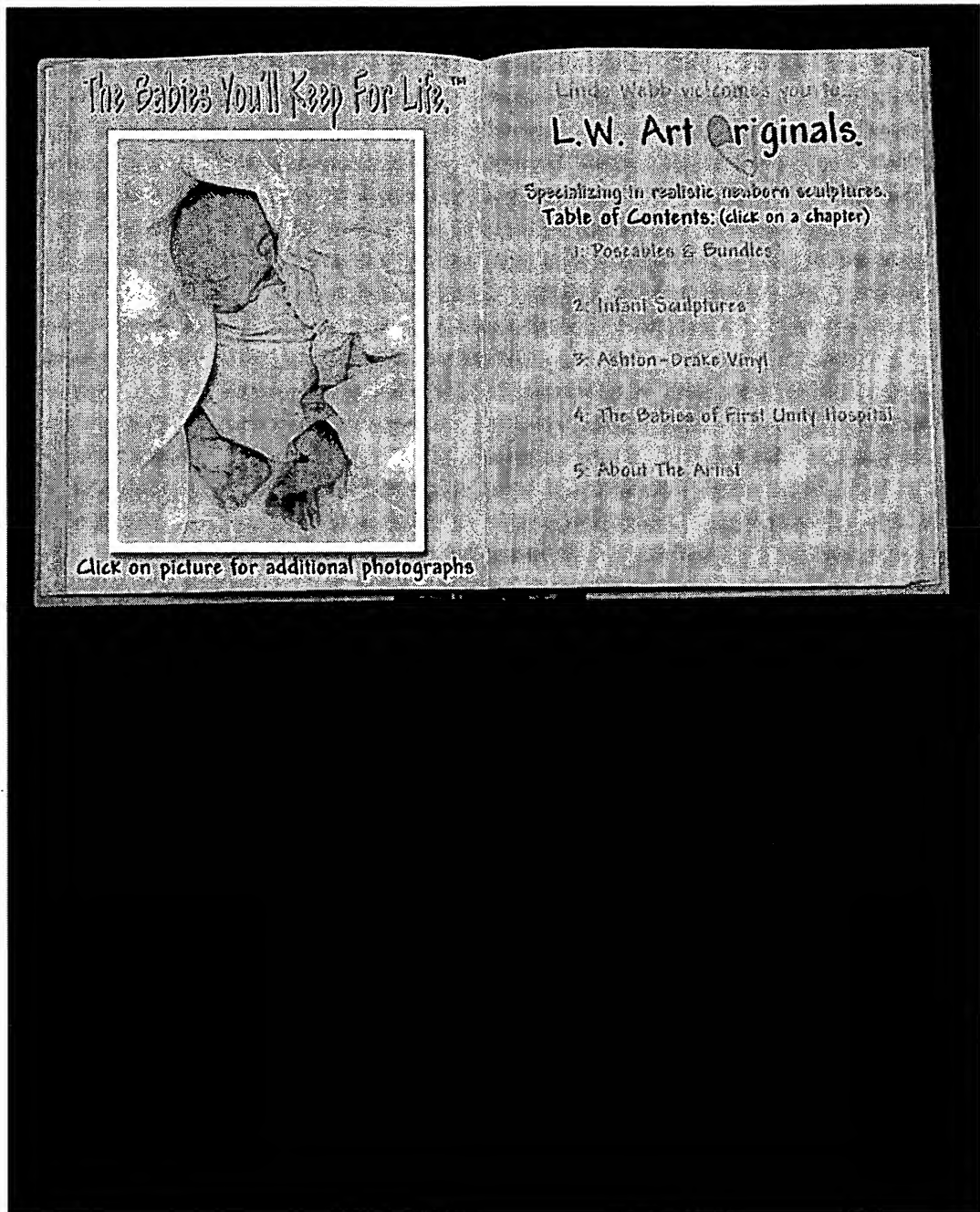
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1 <http://lindawebb.com/contents.htm>

2 LW Art Originals - Table of Contents



19 <http://lindawebb.com/contents.htm> 2/10/2009 2:37:50 PM

1 RELATED CASES SECTION

2 There are no related cases to submit in this section.

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Respectfully submitted,

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